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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,488	05/24/2001	Marcia A. Wise	7733.D2	3552

7590 12/30/2005

FAY KAPLUN AND MARCIN, LLP  
150 BROADWAY, SUITE 702  
NEW YORK, NY 10038

EXAMINER
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SIRMONS, KEVIN C

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

TZth

<b>Office Action Summary</b>	<b>Application No.</b> 09/864,488	<b>Applicant(s)</b> WISE ET AL.	
	<b>Examiner</b> Kevin C. Sirmons	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 October 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 55-66 and 68-81 is/are pending in the application.  
4a) Of the above claim(s) 55, 57 and 58 is/are withdrawn from consideration.  
5) ☒ Claim(s) 80 and 81 is/are allowed.  
6) ☒ Claim(s) 56, 59-66, 68-72 and 74 is/are rejected.  
7) ☒ Claim(s) 75-79 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Drawings (strongly suggested)*

It is strongly suggested that applicant show a catheter including **first and second lumens extending therethrough from a proximal end of the catheter to a distal end** thereof as claimed. Figs. 1 and 3 **clearly do not show** what is claimed.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 56 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 56, it is unclear how applicant a catheter includes a first and second lumens extending therethrough from a proximal end of the catheter to a distal end of the catheter thereof when it appears from the drawings that the catheter has one distal end and two separate proximal ends.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 56, 65-66 and 68-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Fogarty et al U.S. Pat. No. 4,564,014.

Fogarty discloses a system for establishing intermittent fluid communication with a patient's bloodstream, comprising: a catheter (11) including first and second lumens extending therethrough from a proximal end of the catheter to a distal end thereof, wherein, when in an operative position, the distal end of the catheter resides within a blood vessel of a patient (figs. 1-7); a first sealing balloon (14) positionable within a distal end of the first lumen, so that, when inflated, the first balloon, seals the distal end of the first lumen to prevent blood flow thereinto; and a deflation mechanism (30); note: the device of Fogarty is fully capable of providing the function as set forth in the claim. As to claims 65, 68-69, (figs. 1-6)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 59-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty et al U. S. Pat. No. 4,564,014 in view of Burns et al U.S. Pat. No. 5,176,698.

Fogarty discloses the method substantially as claimed except for purging the first lumen. Burns discloses purging the first lumen (abstract and entire specification).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to purge the catheter of Fogarty as taught by Burns to vent unwanted gases and liquids. As to claims 60-62, (Burns col. 2); as to claim 63, (fig. 6); as to claim 64, (The terminating act is performed by purging. See above 103)

Claims 70-72 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipperman U.S. Pat. No. 5,092,839.

Kipperman discloses a catheter substantially as claimed except or companion ingress and egress side-by-side non-concentric catheter tubes. (Applicant is merely attempting to claim two of the identical aforementioned tubes not having a common center). It would have been obvious to one of ordinary skill in the art at the time the invention was made to duplicate the device of Kipperman, since it has been held that mere duplication of essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, USPQ 8; as to claim 71, (14/16, the examiner regards the hollow tube (13/16) as the stem); as to claim 72, (9, col. 3, lines 39-45); as to claim 74, (the manifold 6 has a port which can be used to flush liquid (col. 3, lines 30-45).

#### ***Allowable Subject Matter***

Claims 75-79 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 80 and 81 are allowable over the prior art of record.

### ***Response to Arguments***

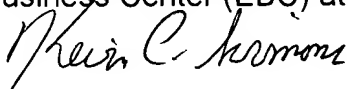
Applicant's arguments with respect to claims 56 and 59-79 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Sirmons whose telephone number is 571-272-4965. The examiner can normally be reached on Monday-Friday 6:30-4:00 ALT FRI.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Kevin C. Sirmons  
Primary Examiner  
Art Unit 3767  
12/27/05